July 27, 2020

Volcano Corporation
Brian Park
Sr.Regulatory Specialist
3661 Valley Center Dr
Suite 200
San Diego, California 92130

Re: K123482
Trade/Device Name: ReFLOW Aspiration Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ

Dear Brian Park:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated April 29, 2013. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S

Digitally signed by Gregory W. O'connell -S
Date: 2020.07.27 07:55:58 -04'00'

Gregory O'Connell
Assistant Director
Plaque Modification Devices Team
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 29, 2013

Volcano Corporation
Brian Park, Senior Regulatory Affairs Specialist
3661 Valley Centre Drive, Suite 200
San Diego, CA 92130

Re: K123482
Trade/Device Name: ReFLOW Aspiration Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: April 25, 2013
Received: April 26, 2013

Dear Mr. Park:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for

Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

5l0(k) Number K123482

Device Name ReFLOW® Aspiration Catheter

Indications for Use The ReFLOW Aspiration Catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the coronary, carotid and peripheral vasculature.

Prescription Use ___X____ OR Over the Counter Use _____
(Per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Matthew G. Hillebrenner

510(K) SUMMARY

SPONSOR:

Volcano Corporation
3661 Valley Centre Drive Suite 200
San Diego, CA 92130

CONTACT/SUBMITTER:

Brian Park
Senior Regulatory Affairs Specialist
Volcano Corporation
3661 Valley Centre Dr. Suite 200
San Diego, CA 92130
Tel: (858) 720-4176

DATE OF SUBMISSION:

April 5, 2013

DEVICE:

Volcano ReFLOW® Aspiration Catheter

Trade Name: ReFLOW Aspiration Catheter
Common Name: Catheter, Embolectomy
Classification: 21 CFR Part 870. 5150
Class II Device

PREDICATE DEVICE:

Lumen Medical Xtract Aspiration Catheter

DEVICE DESCRIPTION:

The ReFLOW Aspiration Catheter is an embolectomy catheter comprised of a catheter shaft and hub. It is 150cm long and is available in 6F and 7F diameters.

INDICATIONS FOR USE:

The ReFLOW Aspiration Catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the coronary, carotid and peripheral vasculature.

COMPARISON OF CHARACTERISTICS:

The proposed device is substantially equivalent to the predicate device. Both devices are aspiration catheters consisting of a catheter shaft and hub. The proposed ReFLOW Aspiration Catheter is offered in two sizes, identical to the predicate device. The outer and inner shaft diameters are identical for both the predicate and proposed devices.

PERFORMANCE DATA:

Non-clinical device testing was conducted to confirm the performance of the device. Bench testing was conducted against known standards or product specifications and evaluated the following:

- Dimensional Verification
- Visual Inspection
- Particulate Evaluation
- Tube to Stopcock Tensile Strength
- Tube to Luer Tensile Strength
- RX Notch Tensile Strength
- Hub to Shaft Tensile Strength
- Loading Tool Tensile Strength
- Liquid Leak Pressure Test
- Wall Integrity Test
- Guidewire Loading Test
- Torque Strength
- Coating Adhesion Test
- Kink Resistance
- Liquid Aspiration Leak Test
- Aspiration Flow Rate
- Thromboemboli Aspiration Simulated Use Testing

Biocompatibility testing was conducted on the device and the following tests were successfully completed:

- Cytotoxicity
- Intracutaneous
- Systemic Toxicity
- Maximum Sensitization
- Material Mediated Pyrogen
- ASTM Hemolysis
- *In Vitro* Hemolysis
- C3a Complement Activation
- SC5-b Complement Activation
- Partial Thromboplastin Time
- *In vivo* Thromboresistence
- Limulus Amebocyte Lysate

Completion of these tests concluded the ReFLOW catheter is substantially equivalent to the predicate device.